IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

GAYLE ROSE,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	**No. 07-2404 Ml/P**
MATRIXX INITIATIVES, INC. and ZICAM, LLC,	)	
	)	
Defendants.	)	
	)	
	)	
	)	

REPORT AND RECOMMENDATION ON DEFENDANTS' MOTION TO EXCLUDE THE EXPERT REPORT AND TESTIMONY OF TERENCE M. DAVIDSON, M.D.

Before the court is defendants Matrixx Initiatives, Inc. and Zicam, LLC's (collectively "Matrixx") Motion to Exclude the Expert Report and Testimony of Plaintiff's Expert, Terence M. Davidson, M.D. (D.E. 31). This motion was referred to the Magistrate Judge for a report and recommendation. Pursuant to the order of reference, the court held an evidentiary hearing on the motion. Counsel for all parties were present and heard. At the hearing, Rose did not call Dr. Davidson as a witness, but instead relied on Dr. Davidson's expert report, deposition testimony, and various exhibits. At the conclusion of the hearing, the court took the matter under advisement.

The court has now considered the arguments of counsel, briefs

submitted in support of and in opposition to the motion and attached exhibits, exhibits to the evidentiary hearing, Dr. Davidson's report and deposition testimony, and the deposition testimony of other key witnesses, including Rose and Dr. Dean A. Klug, one of Rose's treating physicians.[1] Based on the entire record, the court proposes the following findings of fact and conclusions of law, and recommends that the Motion to Exclude be granted.

I. PROPOSED FINDINGS OF FACT

Matrixx manufactures and distributes Zicam Cold Remedy No Drip Liquid Nasal Gel ("Zicam"), a homeopathic cold remedy intended to place zinc in direct contact with the nasal epithelial membrane. The active ingredient in Zicam is zinc gluconate, which is supposed to reduce the length and severity of a cold. Zicam is delivered to the nasal membrane by a small, hand-held pump. The printed instructions found on the Zicam packaging direct the user to place the applicator tip one-eighth of an inch past the nasal opening, angle the nozzle slightly outward, and pump the applicator once in each nostril. The instructions also direct the user not to "sniff up" the gel, in order to avoid irritation.

In February of 2006, Rose purchased a package of Zicam from a Walgreens store in Memphis, Tennessee. On May 18, 2006, while

[1]Dr. Davidson was deposed on May 4, 2008, and relevant portions of his deposition transcript are attached as exhibits to Matrixx's motion and Rose's response.

attending a seminar at a Memphis hotel, Rose felt a "tickle" in her throat and became concerned that she was coming down with a cold. She went to the restroom and removed the sealed Zicam from her purse. According to Rose's deposition testimony, she used the Zicam according to the directions on the package and applied it only to her left nostril:

> Q: You bought that [Zicam] in February of 2006. Did you take the container out of the box at that time?
>
> A: When I arrived at home.
>
> Q: And then did you discard the box and any inserts that were in it?
>
> A: After I read the inserts and the back of the box, I discarded it, yes.
>
> Q: All right. So they had been discarded the same day you bought it?
>
> A: Yes, because I put it [sic] my purse.
>
> Q: And that was about three months before you actually used it?
>
> A: Yes.
>
> Q: So the only thing that you put in the purse is the container itself?
>
> A: The little – the medicine itself.
>
> Q: Now, the box that it came in did have an insert in it; is that correct?
>
> A: Yes, to my knowledge it did.
>
> Q: And do you recall – did you read that insert?
>
> A: It is my standard practice to do so because I always read the inserts. I always read the inserts to any over-the-counter or prescribed medicine.

Q: Do you recall whether the insert contained directions on how to use the Zicam?

A: Yes. Whether it was on the insert or whether it was on the back of the box, I can't recall, but I know there were directions.

Q: And as of May, 2006, three months after you had read those, do you think you recall what those directions for use were?

A: Yes, because they were unusual.

. . . .

Q: I want you to tell me as much detail exactly how you went about applying the gel?

A: Well, I took the thing [plastic cap] off and the only thing I do remember is that the instructions said to point it toward the side of your nose. That's one thing I remember. And I took – squirted it into my left nostril and immediately went into writhing pain. *My right nostril never got any.*

Q: When you inserted the tip . . . into your left nostril, can you estimate how far up your nostril you put it before you actually applied the gel?

A: Well, no. I didn't put it too far because then it feels – makes you feel like you're going to sneeze, so I just put it right on the inside and squirted it.

. . . .

Q: Can you estimate how far you had it up your nose when you – when you squirted? Was it quarter of an inch, half inch, inch.

A: Probably not an inch. Probably a quarter of an inch, yeah.

. . . .

Q: Okay. When you inserted the gel on May 18 in the ladies' restroom, after inserting, did you sniff it up?

> A: *I think that – I don't really recall whether I sniffed it up or not. I know it's a natural reaction when you have something in there to sniff it up, but I don't recall whether I actually – whether that – I sniffed or not.*
>
> Q: Okay. After you applied it, did you press on your nostril at all either from the side or from the front?
>
> A: I mean, when I was in writhing pain I was like this (indicating). You know, it was so bad I almost vomited from the pain.
>
> Q: *And you never applied anything to your right nostril, correct?*
>
> A: *No.*

(Rose Dep. at 44-45, 130-31, 133, 137-38) (emphasis added).[2]

Immediately after applying the Zicam, Rose felt "excruciating, painful sinus and head pain" above her nose and between her eyebrows that lasted for about half an hour. Rose remained in the restroom until the pain subsided, at which time she left the

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[2]Rose was deposed on January 10, 2008, and relevant portions of her deposition transcript are attached as exhibits to Matrixx's motion and Rose's response. In addition to testifying at her deposition that she sprayed the Zicam into only her left nostril, on February 29, 2008, she was examined by an independent medical examiner, Dr. James A. Duncavage, a professor in the Department of Otolaryngology at Vanderbilt University Medical Center and an expert in rhinology and sinus disorders. Rose told him during the examination that she sprayed the Zicam into only her left nostril and did not spray it into her right nostril. (Ex. F to Matrixx's Mot.). The court notes that Rose was examined by Dr. Duncavage after she was examined by Dr. Davidson on February 11 and 12, 2008, discussed infra, during which time Dr. Davidson informed her that because she suffered from bilateral smell loss, she must have sprayed the Zicam into both nostrils and simply forgotten what had happened. (Davidson Dep. at 11-13). Despite Dr. Davidson's comment to her, Rose reported to Dr. Duncavage two weeks later that she sprayed the Zicam into only her left nostril, consistent with her deposition testimony.

seminar and went home for the rest of the day to recover from the experience.

Approximately two days later, Rose discovered that she had lost her sense of smell and taste. On May 22, 2006, Rose sought treatment from Dr. Dean A. Klug, an Ear, Nose, and Throat specialist.[3] The medical history form that Rose filled out during her initial visit with Dr. Klug states, "Thursday I took 1 dose of Zicam into left nostil [sic] extreme pain & burning, lasting 15-20 mins." (D.E. 31-5 at 1). Dr. Klug's examination revealed that Rose had a nasal septal deviation to the left, nasal congestion, and swollen turbinates. On that initial visit, Dr. Klug diagnosed decreased smell and left deviated septum for which he prescribed Levaquin, Rhinocort, and a nasal saline irrigation:

> Q: And it indicates that there was nasal mucosa congestion that you found?
>
> A: Right.
>
> Q: Tell us what that is.
>
> A: The linings were swollen more, just a degree more than what you would normally see. There was narrowing of the space.
>
> Q: Is that a cold symptom or a sinus symptom or something you would typically expect to find in somebody who has a sinus problem or cold?
>
> A: The nose is irritated.

[3]Dr. Klug was deposed on January 31, 2008, and relevant portions of his deposition transcript are attached as an exhibit to Matrixx's motion.

Q: If she had a cold or has a cold coming on, or if any patient has had a cold or a cold coming on, you would expect to find some irritation; is that fair?

A: Yes, correct, allergy, anything.

Q: Irrespective of whether they had sprayed anything in their nose or not, is that right?

A: Yes.

Q: The nasal mucosa congestion, was it significant or minor?

A: It was not – it wasn't severe.

Q: And then you also indicate that the turbinates were swollen?

A: Yes.

Q: First of all, what is that?

A: Those are structures inside the nose that are normal structures that are there to filter air and warm the air. And they can swell in response to irritation.

Q: Is that something you would expect to find in somebody who has a cold, cold related symptoms?

A: You could see that.

Q: Irrespective of whether they had sprayed anything in their nose or not?

A: Yes.

Q: So, your examination on that initial day, did you, other than the subjective complaint or finding, that is that Ms. Rose said she couldn't smell, but, objectively, did you find anything that you would not expect to find in somebody who had a cold or a cold coming on?

A: No. I think the thing that concerned me that day was just the close – the relationship between her having the onset of these symptoms and then her spraying the – I mean, it all started after she sprayed her nose.

(Klug Dep. at 59-62).

Dr. Klug treated Rose several more times through the end of 2006 for complaints of decreased smell and taste, and he conducted a series of smell tests. He diagnosed her with chronic rhinitis (nasal congestion and irritation) and anosmia. Rose was last examined by Dr. Klug on December 15, 2006, for complaints of laryngitis, sore throat, and congestion. The nasal examination notes from that visit state "nasal mucosa swollen, congested. Inferior turbinates are swollen." An x-ray of the sinuses was taken, and the medical notes indicate "significant nasal congestion as well as right maxillary air/fluid level." Dr. Klug diagnosed "right maxillary sinusitis, chronic rhinitis, chronic anosmia, laryngitis," and he prescribed antibiotics.

On May 16, 2007, Rose filed the present lawsuit against Matrixx, alleging that the Zicam caused her anosmia. On February 11 and 12, 2008, Rose was examined by Dr. Terence Davidson, Professor of Head and Neck Surgery at the University of California-San Diego ("UCSD") and Director of the UCSD Nasal Dysfunction Clinic. During that visit, Rose was initially examined by Dr. Davidson's colleague, Dr. William Cain, who took Rose's medical history and performed a smell test. Rose told Dr. Cain that she did not spray the Zicam into her right nostril. During the subsequent examination by Dr. Davidson on February 12, Rose repeated to Dr. Davidson that she sprayed the Zicam only into her

left nostril. At that point, Dr. Davidson "confronted" Rose about her statement, since he knew that Rose suffered from bilateral smell loss and knew that the Zicam could not have caused her anosmia if, in fact, she had only sprayed it into her left nostril. As Dr. Davidson testified at his deposition,

> Q: You made a specific note in your chart that there was bilateral – I'm sorry, that your impression was that she sprayed both sides. It's your understanding that she has bilateral smell loss?
>
> A: Yes.
>
> Q: That means smell loss in each nostril?
>
> A: Correct.
>
> Q: Why did you put in your note that it was your impression that she sprayed both sides?
>
> A: When she presented to me, she had expressed the opinion, both in deposition and to others, that she had only sprayed it in one or the other side. This made no physiologic sense that one could spray a toxin into one side of the nose, absent a large septal perforation and have it destroy the olfactory receptors in both sides.
>
> So I had a discussion with her, which I actually quite remember, in which I confronted her and said, "You obviously – you had to have sprayed it in both sides. And either from the trauma of the moment or whatever, you have forgotten that." And there was this sort of look of shock on her face as she comprehended this and realized that perhaps she had made a mistake.
>
> Having found no other plausible cause for her to have had this acute smell loss and believing that it had to be an acute toxin-induced injury, whether she recalled it specifically or the trauma of the moment had obscured her memory, it was my opinion that she sprayed it on both sides and she suffered, as a direct result of that, a bilateral zinc-induced anosmia.
>
> . . . .

> Q: What specifically did she tell you?
>
> A: The precise wording and circumstances, I don't know, but she told me that story. I had – I knew the issue because Mr. Shannon [plaintiff's counsel] had told me the issue and because Dr. Cain's report also contained her claim at that point that she had only used it on one side, so I knew that this was an issue in coming, and she provided the same to me, and then we had the discussion which I just told you of.

(Davidson Dep. at 11-13).

Dr. Davidson seeks to offer the expert opinion that Rose has suffered and continues to suffer from zinc-induced anosmia and that the condition was caused by her use of the Zicam. To support his opinion on general causation, Dr. Davidson offers the opinion that Zicam is toxic to the olfactory epithelium. He does not, however, offer any opinion on whether it is possible for Zicam to reach the olfactory epithelium.[4] In the present motion, Matrixx seeks to exclude Dr. Davidson's opinions on the grounds that they fail to

[4]In the section of his report titled "Zinc Induced Anosmia," Dr. Davidson states that "it is my opinion, to a reasonable degree of medical certainty, that zinc gluconate nasal gel, squirted and sniffed into the nasal cavity, does, in a small group of patients, reach the olfactory cleft, destroy the olfactory epithelium and receptors, and cause permanent smell loss, a condition called anosmia." (D.E. 33, Ex. U). Also, during his deposition, Dr. Davidson testified that he did not know whether or not Zicam can reach the olfactory cleft by a "straight shot," but he believed that "one somehow deposits the gel into the nasal cavity and then gives it a sniff, and that it is that sniff in a small number of people which pulls it up into the olfactory cleft and where the damage occurs." (Davidson Dep. at 17). However, in Rose's response in opposition to the Motion to Exclude Dr. Davidson, she states that Dr. Davidson will not offer an opinion on whether zinc gluconate nasal gel can reach the olfactory epithelium. (See Pl.'s Resp. to Mot. To Exclude at 12; see also Pl.'s Resp. to Mot. for Summ. J. at 13).

meet the standards of Fed. R. Evid. 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).[5]

II. PROPOSED CONCLUSIONS OF LAW

A. *Daubert* and Rule 702

In Daubert, the United States Supreme Court held that the Federal Rules of Evidence had superseded the "general acceptance" test of Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), and that Federal Rule of Evidence 702 requires that trial courts perform a "gate-keeping role" when considering the admissibility of expert testimony. Daubert, 509 U.S. at 597. Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

The court's gate-keeping role is two-fold. First, the court must determine whether the testimony is reliable. See Daubert, 509 U.S. at 590. The reliability analysis focuses on whether the reasoning or methodology underlying the testimony is scientifically valid. Id. The expert's testimony must be grounded in the methods and procedures of science and must be more than unsupported

[5]Matrixx does not challenge Dr. Davidson's qualifications as a nasal health expert.

speculation or subjective belief. Id. The proponent of the testimony does not have the burden of establishing that it is scientifically correct, but that by a preponderance of the evidence, it is reliable. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 744 (3d Cir. 1994).

To aid the trial court in its determination of whether an expert's testimony is reliable, the Supreme Court in Daubert set forth several non-exclusive factors to consider: (1) whether the theory or technique has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error of the method used and the existence and maintenance of standards controlling the technique's operation; and (4) whether the theory or method has been generally accepted by the scientific community. Daubert, 509 U.S. at 593-94; see also First Tennessee Bank Nat. Ass'n v. Barreto, 268 F.3d 319, 334 (6th Cir. 2001). In addition, the court may consider "whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying" because the former "provides important, objective proof that the research comports with the dictates of good science." Smelser v. Norfolk Southern Railway, 105 F.3d 299, 303 (6th Cir. 1997). The court may also consider "[w]hether the expert has unjustifiably extrapolated from

an accepted premise to an unfounded conclusion," and rule out opinions that make too great of an analytical leap from premise to conclusion. Fed. R. Evid. 702 advisory committee's note (citing General Elec. Co. V. Joiner, 522 U.S. 136, 146 (1997)). Another factor that may be considered by the court is "[w]hether the expert has adequately accounted for obvious alternative explanations." Fed. R. Evid. 702 advisory committee's note (citing Claar v. Burlington N.R.R., 29 F.3d 499 (9th Cir. 1994)). Finally, the court may consider "[w]hether the expert 'is being as careful as he would be in his regular professional work outside his paid litigation consulting.'" Fed. R. Evid. 702 advisory committee's note (quoting Sheehan v. Daily Racing Form, Inc., 104 F.3d 940, 942 (7th Cir. 1997)).

The Supreme Court has emphasized that, in assessing the reliability of expert testimony, whether scientific or otherwise, the trial court may consider one or more of the Daubert factors when doing so will help determine that expert's reliability. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147, 150 (1999). The test of reliability is a "flexible" one, and the Daubert factors do not constitute a "definitive checklist or test," but must be tailored to the facts of the particular case. Id. (quoting Daubert, 509 U.S. at 593); see also Ellis v. Gallatin Steel Co., 390 F.3d 461, 470 (6th Cir. 2004). The particular factors will depend upon the unique circumstances of the expert testimony at

issue. Kumho Tire, 526 U.S. at 151-52.

The second prong of the gate-keeping role requires an analysis of whether the expert's reasoning or methodology can be properly applied to the facts at issue, that is, whether the opinion is relevant. See Daubert, 509 U.S. at 591-93. This relevance requirement ensures that there is a "fit" between the testimony and the issue to be resolved by the trial. See United States v. Bonds, 12 F.3d 540, 555 (6th Cir. 1993). Thus, an expert's testimony is admissible under Rule 702 if it is predicated upon a reliable foundation and is relevant.

Although a witness may be qualified as an expert in one area of expertise, the expert may be precluded from offering opinions beyond that area of expertise or which are not founded on a reliable methodology. See, e.g., Kumho Tire, 526 U.S. at 154-55; Allison v. McGhan Medical Corp., 184 F.3d 1300, 1317-19 (11th Cir. 1999); Weisgram v. Marley Company, 169 F.3d 514, 518 (8th Cir. 1999); Cummins v. Lyle Indus., 93 F.3d 362, 371 (7th Cir. 1996). The rejection of expert testimony, however, is the exception rather than the rule, and "the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system." Fed. R. Evid. 702 advisory committee's notes (2000 amendment) (quoting United States v. 14.38 Acres of Land, 80 F.3d 1074, 1078 (5th Cir. 1996)). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the

traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596. Finally, the proponent of the evidence has the burden of establishing that all of the pertinent admissibility requirements are met by a preponderance of the evidence. See Fed. R. Evid. 104(a); see also Bourjaily v. United States, 483 U.S. 171, 175-76 (1987); Smelser, 105 F.3d at 303; West Tenn. Chapter of Associated Builders and Contractors, Inc. v. City of Memphis, 300 F. Supp. 2d 600, 602-03 (W.D. Tenn. 2004).

B. Cases Involving *Daubert* Challenges to Nasal Health Experts

The parties have cited, and the court in conducting its own research has found, several federal cases that involve challenges to the testimony of nasal experts under Daubert and Fed. R. Evid. 702. A review of the case law in this area reveals that the federal courts have consistently excluded the opinions of plaintiffs' nasal experts, including Dr. Davidson, in cases where plaintiffs have suffered smell loss after using Zicam or a similar zinc-gluconate nasal gel spray. See Polski v. Quigley Corp., 538 F.3d 836, 841 (8th Cir. 2008) (Cold-Eeze nasal spray) ; Lusch v. Matrixx Initiatives, Inc., No. 05-292-HA, 2007 WL 2816203, at *4-5 (D. Ore. Sept. 25, 2007) (Zicam); Wyatt v. Matrixx Initiatives, Inc., No. 2:04-cv-1230-UWC, 2007 U.S. Dist. LEXIS 67986, at *14-17 (N.D. Ala. Mar. 30, 2007) (Zicam); Salden v. Matrixx Initiatives, Inc., No. 06-10277, 2007 WL 850239, at *4 (E.D. Mich. Mar. 16,

2007) (Zicam); Hilton v. Matrixx Initiatives, Inc., No. 4:04-CV-519-Y, 2007 U.S. Dist. LEXIS 73264, at *7 (N.D. Tex. Feb. 20, 2007) (Zicam); O'Hanlon v. Matrixx Initiatives, Inc., No. CV 04-10391 AHM (JTLx), 2007 WL 2446496, at *3-4 (C.D. Cal. Jan. 3, 2007) (Zicam); Benkwith v. Matrixx Initiatives, Inc., 467 F. Supp. 2d 1316, 1332 (M.D. Ala. 2006) (Zicam); Sutherland v. Matrixx Initiatives, Inc., No. 04-AR-0129-M, 2006 U.S. Dist. LEXIS 96652, at *41 (N.D. Ala. Nov. 7, 2006) (Zicam); Hans v. Matrixx Initiatives, Inc., No. 3:04CV-540-R, 2006 WL 5229820, at *8 (W.D. Ky. Sept. 29, 2006) (Zicam); see also Best v. Lowe's Home Centers, Inc., No. 3:04-CV-294, 2008 WL 2359986 (E.D. Tenn. June 5, 2008) (excluding expert under Daubert where plaintiff developed anosmia after exposure to concentrated pool chemicals).[6]

In Lusch v. Matrixx Initiatives, Inc., plaintiff Barbara Lusch used Zicam nasal spray when she felt a cold coming on and immediately felt a painful burning sensation. She subsequently realized that her sense of smell was severely diminished and distorted. Lusch, 2007 WL 2816203, at *1. Lusch did not develop a cold after her use of Zicam. Id. Lusch's treating physician,

[6]Dr. Davidson apparently provided expert testimony in the case of Angelo Bruno v. Matrixx Initiatives, Inc., No. GIC 868821, filed July 7, 2006, in state court in California. It is unclear, however, from the record before the court what, if any, opinions were challenged on Daubert grounds in Bruno and to what extent those opinions were admitted at trial. In any event, the court finds the analyses contained in the federal cases cited above to be particularly persuasive on the issues raised in the case at bar.

Dr. Edsel U. Kim, preliminarily diagnosed her with parosmia, a partially distorted sense of smell, approximately one month after her use of Zicam. Id. Dr. Kim later changed Lusch's diagnosis to severe microsmia (greatly diminished sense of smell) and dysosmia (a distorted sense of smell). Id.

Lusch's expert, Bruce W. Jafek, M.D., offered the opinion that (1) Zicam gel is capable of reaching the olfactory epithelium, (2) Zicam is toxic to the olfactory epithelium, and (3) Zicam is delivered in a dose sufficient to cause permanent damage to the olfactory epithelium. Id. at *3. The Lusch court found Dr. Jafek's opinions to be unreliable for several reasons. First, the court found that there was insufficient medical evidence to support the opinion that Zicam could actually reach the olfactory epithelium. Dr. Jafek conceded that Zicam could not reach the olfactory epithelium if sprayed laterally into the nose, but maintained that it was possible for the gel to reach the epithelial tissue if sprayed vertically. Id. In support of this opinion, Dr. Jafek relied upon a study he performed using two cadavers that were sectioned through the septum, in which he sprayed Zicam vertically into the nasal cavity and observed Zicam reach the olfactory epithelium. The Lusch court found this study to be insufficient to support Dr. Jafek's opinion, because he sprayed the Zicam vertically, instead of laterally, as required by the directions on the Zicam package. Id. at *4.

Second, the Lusch court found Dr. Jafek's causation opinion to be unreliable because he failed to sufficiently demonstrate that Zicam is toxic to the olfactory epithelium. Id. To prove toxicity, Dr. Jafek relied primarily on data from polio prevention experiments from the 1930's, in which zinc sulfate was applied to the olfactory epithelia of children, many of whom later complained of anosmia. Dr. Jafek opined that the zinc gluconate in Zicam is toxic in a manner similar to the zinc sulfate in the polio experiment. The court, however, found that "Dr. Jafek's analogy between zinc sulfate and zinc gluconate is an unjustifiable extrapolation from an accepted premise to an unfounded conclusion," because he "failed to show that the differences in chemical structures between the two compounds did not make a difference." Id.

Third, the Lusch court found that Dr. Jafek failed to demonstrate that the dose of Zicam delivered by a spray is sufficiently large to permanently damage the olfactory epithelium. Id. In an attempt to establish toxicity of Zicam, Dr. Jafek relied on toxicity studies performed on animals. However, the court found that the differences between humans and animals made this comparison scientifically insufficient. Id. at *5. As a result of these deficiencies in his opinion, the court excluded Dr. Jafek's opinions.

In O'Hanlon v. Matrixx, plaintiff Dennis O'Hanlon used Zicam

in February of 2003, after experiencing cold symptoms. O'Hanlon, 2007 WL 2446496, at *1-3. After using the product, he felt pain in his sinuses and, shortly thereafter, he experienced smell loss which he alleged was permanent anosmia caused by the Zicam. In that case, the court excluded the expert opinions of Dr. Jafek. The court found that the studies upon which he relied for the dose-response relationship had been neither published nor peer reviewed. The court observed that Dr. Jafek's opinions regarding toxicity came after the litigation, rather than being borne of his own independent research. In addition, Dr. Jafek failed to show that the polio studies upon which he relied, which involved exposure to zinc sulfate (as opposed to zinc gluconate), were performed with an amount of zinc similar to or less than that contained in a dose of Zicam. Finally, the court found that Dr. Jafek had failed to adequately account for alternative explanations for O'Hanlon's anosmia. Id. at *2-3. The court concluded that the combination of these factors rendered Dr. Jafek's causation opinion testimony unreliable, and therefore, inadmissible.

O'Hanlon also retained Dr. Davidson, the expert involved in the present case, as a causation expert in his case. Id. at *3. Dr. Davidson was also of the opinion that the Zicam use had caused O'Hanlon's anosmia. The court excluded Dr. Davidson's testimony "primarily because he fails to establish the dose-response relationship and does not adequately rule out possible alternative

causes of O'Hanlon's anosmia." Id. Specifically, Dr. Davidson failed to adequately establish the dose-response relationship in that he did not discuss the amount of zinc in a single dose of Zicam, the amount of that dose that likely reached the olfactory epithelium, or how that amount compared to the amount of zinc administered in his studies. Additionally, Dr. Davidson did not examine other potential causes of O'Hanlon's anosmia, such as an infection, medication, or exposure to another chemical substance. The court found this failure to rule out other potential causes of O'Hanlon's anosmia raised "serious doubt" about Dr. Davidson's testimony on specific causation. Id.

In Sutherland v. Matrixx, plaintiff Janie Sutherland used Zicam in accordance with the written directions in December of 2001, after experiencing two days of cold symptoms. Sutherland, 2006 U.S. Dist. LEXIS 96652, at *3, *9. Immediately after using the Zicam, Sutherland felt a burning sensation in both nostrils. Shortly thereafter, she lost her ability to both taste and smell. Id. at *9. Dr. Jafek again was prepared to testify to both specific and general causation, including the ability of Zicam to reach the olfactory epithelium and the toxicity of Zicam to the olfactory epithelium. First, Dr. Jafek opined that Zicam could reach the olfactory epithelium, using the same cadaver study considered and rejected in Lusch. See Lusch, 2007 WL 2816203, at *4. The Sutherland court found the cadaver study to suffer from

several methodological flaws which collectively rendered it insufficient to support Dr. Jafek's conclusion. Sutherland, 2006 U.S. Dist. LEXIS 96652, at *22. In an attempt to provide further support for his opinion that Zicam can reach the olfactory epithelium, Dr. Jafek cited two additional studies. The court found his reliance on these studies to be insufficient, as Dr. Jafek had not even read one of the studies, and because the other study was a case study which standing alone was not enough to support his opinion. Id. at *24. The court also discounted Dr. Jafek's reliance on the polio studies, as he did not demonstrate that zinc sulfate and zinc gluconate have the same toxic effect on the olfactory epithelium. Id. at *27. Additionally, the court found the administration of the zinc sulfate in the polio study to be significantly different from the administration of zinc gluconate by a Zicam user. In the polio study, zinc sulfate was administered either by placing an atomizer deep in the nasal cavity or by flooding the nasal cavity with liquid zinc sulfate while the patient held his or her head upside down. Id. at *29. The court observed that nothing approaching either of these methods of administration occurs when Zicam is used according to directions. Id.

The court also found problematic Dr. Jafek's dose-response analysis. Although Dr. Jafek had not demonstrated that any zinc was delivered to the olfactory epithelium in a dose of Zicam, he

nevertheless based his toxicity calculations on a full dosage of zinc (140 microliters) reaching the smell tissue. The court dismissed this calculation, stating that it "defies logic and enters the never-never land of wishful thinking." Id. at *32. The court also rejected Dr. Jafek's use of animal studies to support his dose-response calculations, as the assumption that humans and animals would respond in the same way to zinc exposure was not supported by the medical evidence. Id. at *33.

C. Defendants' Motion to Exclude Dr. Davidson

In this toxic tort case, Rose must show both general and specific causation. Knight v. Kirby Inland Marine, Inc., 482 F.3d 347, 351 (5th Cir. 2007). General causation is "whether a substance is capable of causing a particular injury or condition in the general population." Id. at 351. If Rose is able to demonstrate general causation, she must then demonstrate specific causation through reliable evidence, that is, "whether a substance caused a particular individual's injury." Id.; see also McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1239 (11th Cir. 2005) (stating that "Plaintiffs' experts must offer reliable opinions about Metabolife's general toxicity for the harm Plaintiffs allege and that it in fact harmed them."); Norris v. Baxter Healthcare Corp., 397 F.3d 878, 881 (10th Cir. 2005) (explaining that "Plaintiff must first demonstrate general causation because without general causation, there can be no specific causation."); Downs v.

Perstorp Components, Inc., 126 F. Supp. 2d 1090, 1095 (E.D. Tenn. 1999) (stating that plaintiffs' expert must establish both general causation and specific causation).

1. General Causation

As an initial matter, despite Dr. Davidson's testimony in his deposition that he believes Zicam can reach the olfactory epithelium in a small number of users who vigorously sniff during application, in Rose's response to the present motion to exclude she states that Dr. Davidson will not offer any expert opinion on whether Zicam can reach the olfactory epithelium. (See Pl.'s Resp. to Mot. to Exclude at 12; see also Pl.'s Resp. to Mot. for Summ. J. at 13). Instead, on this critical evidentiary point, Rose relies exclusively on a study conducted in 2005 by Dr. Joseph E. Dohar at the University of Pittsburgh School of Medicine ("Pittsburgh study").[7] The problem with Rose's approach, however, is that all of Dr. Davidson's opinions rely on the fundamental premise that Zicam can reach the olfactory epithelium when used as directed. "Daubert's requirement that the 'expert testify to scientific knowledge – conclusions supported by good grounds for each step in the analysis – means that any step that renders the analysis unreliable under the Daubert factors renders the expert's testimony

[7]The court notes that Dr. Davidson did not rely on the Pittsburgh study in formulating any of his opinions. At his deposition, he testified that he had not read the Pittsburgh study. (Davidson Dep. at 105-06).

inadmissible.'" Hans, 2006 WL 5229820, at *8 (quoting Amorgianos v. AMTRAK, 303 F.3d 256, 267 (2002)).

With respect to the Pittsburgh study, the court submits that the study does not support Rose's argument that Zicam can reach the olfactory epithelium when used as directed, even taking into account the possibility that the user sniffs up the Zicam during application. Hans, 2006 WL 5229820, at *4 (finding that the Pittsburgh study did not provide the required support for Dr. Jafek's opinion that Zicam can deliver zinc ions to the olfactory epithelium). The study, which was conducted at the request of Matrixx, involved twenty-three subjects who were administered a dye using the Zicam spray applicator. The study showed that, when used in accordance with the directions on the package, the dye did not reach the olfactory cleft in any of the subjects, even for those subjects who were artificially decongested by testers prior to application. The study found that when the subjects were maximally decongested by testers and instructed to apply the spray contrary to the directions on the Zicam package, specifically by (1) inserting the tip of the applicator maximally into the nostril, (2) directing the tip of the applicator as superiorly as possible towards the olfactory cleft, and (3) vigorously sniffing during application, four of the twenty-three subjects showed signs of the dye reaching the "region close to the olfactory cleft." (D.E. 32-6). However, as Dr. Dohar explained in his October 15, 2005,

letter, "[i]t was not possible to identify with certainty whether this region was olfactory epithelium or, more likely, epithelium just anterior to the olfactory epithelium." Moreover, Dr. Dohar explained that

> [w]e did not study sniffing as an independent variable in our study. As stated in response #2, vigorous sniffing coupled with the other three instructions that are contrary to those in the package insert rendered the result described above. We would have to study sniffing alone without the other three alterations to know what contribution to superior excursion of the Zicam vehicle was attributed to this one variable.

(Id.). Thus, the study did not address the issue of whether a "vigorous" sniff is capable of delivering Zicam to the olfactory epithelium when the user otherwise complies with the instructions on the package.

In addition, in his expert report and at his deposition, Dr. Davidson was not able to offer any scientific support for his belief that Zicam is capable of reaching the olfactory epithelium, other than his case study of seventeen patients who came to his clinic between October 2002 and August 2005, and reported using a zinc-gluconate nasal gel spray such as Zicam, sniffing "deeply" or "forcefully" while administering the product, experiencing immediate severe burning, and then experiencing a loss of smell.[8]

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[8]When asked at his deposition about his theory that Zicam reaches the olfactory epithelium through a vigorous sniff, Dr. Davidson testified as follows:

> Q: Have you studied that question, what type of sniff is needed to draw gel to the upper regions of the nose?

(D.E. 32-11). However, even in his case study, Dr. Davidson could only state that *"[i]t would not seem unlikely* that a strong sniff *could* suck the gel up to the olfactory cleft where it would layer out along the cleft and remain in contact with the olfactory epithelium for several minutes as a result of its viscosity." (emphasis added). As Dr. Davidson testified during his deposition, he has not conducted any research or testing to determine if zinc gluconate nasal gel spray can reach the olfactory epithelium. (Davidson Dep. at 97-98). As the court in Polski observed, such a study could easily and ethically be conducted without using zinc or other potential toxin. Polski, 538 F.3d at 840.

Even assuming, *arguendo*, that Rose can rely exclusively on the

---

> A: No.
>
> Q: Are you aware of anyone else who has studied that question?
>
> A: I have looked at some literature, and the more you read, the less they know. There are all sorts of opinions about the sniff and olfaction and the direction, their flow, and I can only say the literature has not reached its last opinion or consensus.
>
> . . . .
>
> Q: Now, since the time you formed that opinion, and you've roughly put that in the time frame of 2002, what research, if any, have you done on the specific subject of whether Zicam can reach the olfactory epithelium when a patient sniffs the gel?
>
> A: None.

(Davidson Dep. at 23, 95).

Pittsburgh study to show that a user of Zicam can deliver zinc to the olfactory epithelium by a "vigorous" sniff, the court submits that Dr. Davidson's opinion that Zicam is toxic to the olfactory epithelium does not meet the standards of Daubert and Rule 702. First, Dr. Davidson's reliance on the Tisdall polio study from 1938 is misplaced. F.F. Tisdall, Persistent Anosmia Following Zinc Sulfate Nasal Spraying, J. Pediatrics, 18: 13, 60-62 (1938). Courts have rejected the use of the polio studies by plaintiffs' experts in Zicam litigation, given the inability by the experts to account for the differences in zinc sulfate used in the polio studies and zinc gluconate found in nasal sprays. See Lusch, 2007 WL 2816203 at *4 (stating that "Dr. Jafek's analogy between zinc sulfate and zinc gluconate is an unjustifiable extrapolation from an accepted premise to an unfounded conclusion"); Wyatt, 2007 U.S. Dist. LEXIS 67986, at *13 (stating that "even small differences in chemical structure can sometimes make very large differences in the type of toxic response that is produced") (internal quotation omitted); O'Hanlon, 2007 WL 2446496, at *2 (stating that Dr. Jafek's extrapolation from the polio experiments was not reliable); Benkwith, 467 F. Supp. 2d at 1327 (stating that "[t]o rely on studies using zinc sulfate, Dr. Jafek must show that the analogy to zinc gluconate is valid by demonstrating that the dissimilarities in chemical structure make no difference in the toxic effect on the olfactory epithelium"); Hans, 2006 WL 5229820, at *5-6 (rejecting

comparison between zinc sulfate and zinc gluconate because expert was unable to demonstrate that the differences in chemical structure did not make a difference *in vivo*); Sutherland, 2006 U.S. Dist. LEXIS 96652, at *26-27 (stating that "there are too many dissimilarities between the experimental application of zinc sulfate to prevent the spread of polio in the 1930s and the use of an over-the-counter cold treatment today. Most importantly, zinc sulfate is chemically distinct from zinc gluconate.").

In his report, Dr. Davidson states in a conclusory manner that "[s]ulfate and gluconate have different molecular weights; therefore, different concentrations by weight have different amounts of cationic zinc. These differences are small and do not affect the zinc cation toxicity." (D.E. 36-4, at p. 17). Although Dr. Davidson in his report discusses in some detail the chemical makeup of zinc sulfate and zinc gluconate, he does not sufficiently demonstrate that the chemical differences between zinc sulfate and zinc gluconate make no difference in the toxic effect on the olfactory epithelium. Benkwith, 467 F. Supp. 2d at 1328. Thus, the court submits that Dr. Davidson's extrapolation of findings from the polio study and application of those findings to the present litigation is not reliable.

Second, Dr. Davidson's toxicity opinion is not supported by any studies of the dose-response relationship, which is "the hallmark of basic toxicology." Benkwith, 467 F. Supp. 2d at 1328

(quoting McClain, 401 F.3d at 1242). As the court in Benkwith explained,

> [d]istrict courts should pay careful attention to an expert's consideration of the dose-response relationship when analyzing her methodology in toxic tort cases. . . . "The dose-response relationship is a relationship in which a change in the amount, intensity, or duration of exposure to an agent is associated with a change – either an increase or decrease – in risk of disease." . . . The reliability of an expert's methodology is suspect if she avoids or neglects the dose-response relationship.

Benkwith, 467 F. Supp. 2d at 1328 (internal citations omitted). In his report, Dr. Davidson merely discusses the importance of demonstrating a dose-response relationship, but stops far short of establishing any kind of dose-response relationship and, in fact, acknowledges that neither he nor anyone else has conducted scientific studies on a dose-response relationship:

> . . . . The dose response curve in zinc induced insomnia is on one hand simple and, on the other, complex. Theoretically, this should be a very simple dose response curve, the greater the zinc concentration the greater the effect i.e. the chemical injury, the greater the damage to the olfactory receptor cells and the greater the anosmia. However, in the current matter dose variation is not so much the zinc cation concentration, for all Zicam has the same molar concentration and *no experiments have been conducted looking at concentration vs. effect*, but rather the nature and time of the contact between the zinc and the olfactory tissue.
>
> The dose variable is the time and of [sic] the contact of the gel with the olfactory cleft. The cleft is variable in location and the distribution of the olfactory receptor cells in the cleft is variable, the nasal anatomy is variable, the direction and spray force are variable, and the presence and strength of the sniff are variable. Therefore how much zinc gel gets to the olfactory cleft is variable. In addition, the time or duration of the exposure is important. Whereas most

> experimental zinc applications use a watery, low viscosity solution, Zicam Cold Remedy Nasal Gel sprays are mixed in a glycerin material that makes the spray a gel, a high viscosity solution. This viscous gel, when deposited in the olfactory cleft, adheres to the tissue and hence the time of contact and the time of exposure are long. This prolonged exposure extends the time of chemical interaction and increases the proteolytic destruction of the olfactory receptor cells. While there is no information regarding the time of exposure, I estimate this at 15 to 20 minutes, based on my experience placing this gel on my own fingers. It is the sum of all of these variables that creates the variation in "dose" and the variation in effect.

(D.E. 36-4) (emphasis added). The O'Hanlon court found Dr. Davidson's inability to establish a dose-response relationship to be problematic:

> In his cited research, Dr. Davidson failed to analyze the dose-response relationship. That is, he did not discuss: (1) how much gel each patient inserted into his or her nose; (2) how much gel likely reached the epithelium; or (3) whether this amount would be comparable to the amount delivered by the Zicam pump. Dr. Davidson did not run any other experiments or rely on other research that reliably demonstrates that Zicam delivers a toxic amount of zinc to the olfactory epithelium. Since he did not consider this data, Dr. Davidson's opinion that Zicam is toxic to the epithelium is not sufficiently reliable to be admissible.

O'Hanlon, 2007 WL 2446496, at *3 (internal footnote omitted); see also Lusch, 2007 WL 2816203, at *4 (stating that "Dr. Jafek's opinion fails because there is no reasonable scientific evidence that Zicam is delivered in a dose sufficient enough to permanently damage olfactory epithelial tissue."); Sutherland, 2006 U.S. Dist. LEXIS 96652, at *31-33 (finding that Dr. Jafek failed to establish a dose-response relationship and explaining that "[u]nless and

until Dr. Jafek can prove that a dose of Zicam sufficient to cause a toxic effect is present in the olfactory neuroepithelium, the fact that zinc gluconate is delivered to the nasal membrane is irrelevant."). Because Dr. Davidson offers no scientific evidence to demonstrate the dose-response relationship, "there is an unsurmountable methodology problem." Sutherland, 2006 U.S. Dist. LEXIS 96652, at *34.

Third, to the extent Dr. Davidson attempts to rely on animal studies to support his opinion that zinc gluconate is toxic to the olfactory epithelium, it is apparent from his own report that the animal studies conducted thus far do not provide reliable support for such an opinion. Indeed, as Dr. Davidson points out in his report, differences in body size, olfactory epithelium area, density of receptors in the olfactory epithelium, and internal nasal anatomy make extrapolation of such data "seriously flawed." Dr. Davidson further states, "mice, rats, and even monkeys are anatomically and physiologically different than humans, so one cannot reliably extrapolate from the animal experiments with zinc sulfate to the human experience with zinc gluconate gel." Dr. Davidson also opines that "[t]he bottom line is one cannot make exact dose comparisons between rodents and humans." Not surprisingly, courts have repeatedly rejected the use of animal studies to support expert opinions regarding the effects of zinc gluconate in humans. See Wyatt, 2007 U.S. Dist. LEXIS 67986, at

*14-15 (excluding expert's use of animal studies because "the dose necessary to cause smell loss in animals will not necessarily have the same impact on humans"); O'Hanlon, 2007 WL 2446496, at *2 (excluding an animal study using zinc sulfate, because the burden is on the expert to demonstrate why extrapolation from one species and substance to others is proper, and the expert failed to meet that burden); Benkwith, 467 F. Supp. 2d at 1328 (generally discrediting expert's use of studies of the effects of zinc sulfate on fish because he failed to account for the differences in species and zinc compounds); Sutherland, 2006 U.S. Dist. LEXIS 96652, at *33 (excluding expert testimony drawn from a mouse study because the expert provided no support for the assumption that the toxicity of zinc would be the same across species).

Fourth, the various case studies that Dr. Davidson uses to support his opinion that zinc gluconate is toxic to the olfactory epithelium do not demonstrate that his opinion is reliable. The first is a one-subject case study prepared by Dr. C.A. DeCook, in which DeCook examined a 47-year-old man who had used Zicam, experienced extreme pain immediately after use, and subsequently experienced anosmia. The patient had no history of chemosensory difficulties and did not have a cold or other viral infection when Dr. DeCook examined him shortly after his use of the Zicam. However, Dr. DeCook opined only that the temporal correlation of zinc gluconate and the inducement of anosmia warranted further

study, and he drew no additional conclusions about the causation of the subject's anosmia. C.A. DeCook, Anosmia Due to Inhalational Zinc: A Case Report, 225 Chem. Sciences 659 (2000).

Dr. Davidson also relies on a ten-patient case study by Dr. Jafek from 2004 and his own seventeen-patient case study from 2006. B.W. Jafek, et al., Anosmia After Intranasal Zinc Gluconate Use, Am. J. Of Rhinology, 18: 137-41 (2004); T.H. Alexander and T. M. Davidson, Intranasal Zinc and Anosmia: The Zinc-Induced Anosmia Syndrome, Laryngoscope 116: 217-20 (Sept. 2006). Dr. Jafek's study analyzed the case histories of ten patients who had each used Zicam and subsequently suffered from either anosmia or severe hyposmia. In Dr. Davidson's study, he examined the cases of seventeen patients who presented with anosmia at his clinic after using Zicam. Each of these patients reported a painful burning sensation immediately after using Zicam, and each subsequently reported a loss of smell within forty-eight hours. Of these seventeen patients, Dr. Davidson determined that fifteen of them suffered from zinc-induced anosmia, largely based on the correlation between the use of Zicam and the development of anosmia, coupled with ruling out possible alternative causes of anosmia in some of the patients.

"A case study does not prove causation." Sutherland, 2006 U.S. Dist. LEXIS 96652, at *30. Rather, a case study is a "mere accoun[t] of medical events. [It] reflect[s] only reported data,

not scientific methodology[,]" and while "case studies may bolster true toxicological data, they are not, standing alone, sufficient to establish general causation." Id. (quoting Rider v. Sandoz Pharm. Corp., 295 F.3d 1194, 1199 (11th Cir. 2002)). Here, as in Sutherland, the case studies relied upon by Dr. Davidson at most show that there may be a correlation between intranasal zinc application and anosmia. Id. at *30-31. However, although the studies may raise questions regarding the possible relationship between anosmia and Zicam, they do not "provide an adequate scientific basis for general causation." Id. at *31; see also McClain, 401 F.3d at 1254 ("case reports raise questions, they do not answer them"). With respect to Dr. Jafek's case reports, these have been rejected by several courts as being insufficient to support his opinion on the toxicity of Zicam. Sutherland, 2006 U.S. Dist. LEXIS 96652, at *31; see also Benkwith, 467 F. Supp. 2d at 1326-27; Wyatt, 2007 U.S. Dist. LEXIS 67986, at *14. The court submits that Dr. Davidson's case study, which involves a very small sample size and no rigorous scientific assessment, does not demonstrate anything more than an indeterminate correlation between Zicam use and smell loss.

Finally, the court notes that Dr. Davidson's opinions were developed in the course of litigation against Matrixx. He prepared his case study with Dr. Alexander in 2006 after he began testifying as a retained plaintiffs' expert in Matrixx litigation and he first

applied the Bradford-Hill causation analysis in February of 2008 at the request of his attorney for the purpose of attempting to satisfy the Daubert standards. Smelser, 105 F.3d at 303.

Based on the above analysis, the court submits that Dr. Davidson's opinions on general causation do not meet the standards of Daubert and Rule 702 and therefore should be excluded.

2. Specific Causation

Based on the court's recommendation that Dr. Davidson's opinions on general causation should be excluded, the court further recommends that his opinions on specific causation also should be excluded, as a plaintiff "must first demonstrate general causation because without general causation, there can be no specific causation." Benkwith, 467 F. Supp. 2d at 1331 (quoting Norris, 397 F.3d at 881); see also Sutherland, 2006 U.S. Dist. LEXIS 96652, at *36 (stating that "[i]f a plaintiff is unable to establish general causation, the need to consider whether the plaintiff has established specific causation disappears."). In any event, Dr. Davidson's opinions on specific causation are seriously flawed, as the uncontradicted evidence demonstrates that Rose did not spray the Zicam into her right nostril and thus the Zicam could not have been the cause of her bilateral smell loss. Rose testified at her deposition that she sprayed the Zicam only into her left nostril. When she first went to see Dr. Klug, she filled out a medical history form and indicated that she sprayed the Zicam into her left

nostril. When she went to see Dr. Davidson after filing this lawsuit, she told both Dr. Davidson and his associate, Dr. Cain, that she did not spray the Zicam into her right nostril. Afterwards, Rose was examined by Dr. Duncavage and she told him that she sprayed the Zicam only into her left nostril. Dr. Davidson's belief that Rose must have sprayed the Zicam into both nostrils and must have simply forgotten what had happened is not supported by any evidence in the record.[9]

III. RECOMMENDATION

For the reasons above, the court recommends that the Motion to Exclude the Expert Report and Testimony of Terence M. Davidson, M.D., be granted.

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[9]Dr. Davidson also opines that, based on his differential diagnosis analysis, there are no other possible explanations for Rose's anosmia. However, this differential diagnosis analysis "only satisfies a Daubert analysis if the expert can show the general toxicity of the drug by reliable methods." Benkwith, 467 F. Supp. 2d at 1331 (quoting McClain, 401 F.3d at 1253). As discussed at length above, Dr. Davidson has not shown the general toxicity of Zicam to the olfactory epithelium. In addition, Dr. Klug diagnosed Rose with nasal congestion and swollen turbinates three days after her use of the Zicam. Dr. Klug further diagnosed her with both chronic rhinitis and sinusitis on subsequent office visits. These symptoms indicate that a viral infection could have been present and could have caused Rose's anosmia. See Benkwith, 467 F. Supp. 2d at 1331-32 (excluding expert testimony on specific causation in part because the expert relied on plaintiff's testimony that she did not develop a cold as basis to rule out virally-induced anosmia, despite other indications, such as plaintiff's decision to use Zicam in the first place, that she may have been suffering from a viral infection).

Respectfully submitted,

s/ Tu M. Pham
TU M. PHAM
United States Magistrate Judge

December 9, 2008
Date

NOTICE

ANY OBJECTIONS OR EXCEPTIONS TO THIS REPORT MUST BE FILED WITHIN TEN (10) DAYS AFTER BEING SERVED WITH A COPY OF THE REPORT. 28 U.S.C. § 636(b)(1)(C). FAILURE TO FILE THEM WITHIN TEN (10) DAYS MAY CONSTITUTE A WAIVER OF OBJECTIONS, EXCEPTIONS, AND ANY FURTHER APPEAL.